Wyoming Department of Health Institutional Review Board Application for Continuing Review or Study Closure: Instructions

Submit the following to the IRB: the completed Application for Continuing Review or Study Closure, a copy of the currently approved informed consent document, and any other supporting material.

General Instructions: This form should be completed one month prior to expiration of a study to ensure continuing approval. The form may be completed electronically, but a printed copy containing an original signature of the PI must be submitted for the files. Continuing review will be done at the IRB meeting following receipt of the completed form. Investigators will be notified of the date and time of the continuing review meeting should they wish to attend. Please email electronic copy to karl.musgrave@health.wyo.gov and forward signed hard copy to:

WDH IRB c/o Karl Musgrave DVM MPH Preventive Health and Safety Division 6101 Yellowstone Road, Suite 510 Cheyenne, Wyoming 82002

Header. The header, which is located at the top of the Application for Continuing Review or Study Closure has a place to list the IRB#, the date of IRB expiration, the PI and the study title. Place your cursor directly on the header and double-click. Once the header is open for editing purposes, input the information.

- 1. **Status of the Research.** Please check the appropriate box that best describes the status of the research project. This form can also be used to close out the research project with the IRB.
- 2. Close the Study. If closing the study completely, please provide a final study report with this application that includes the total number of consented participants, any withdrawals with an explanation for each, and any other pertinent material as it becomes available.
- 3. Summary of the Progress Since Initial IRB Review or Last IRB Continuing Review.
 - **A. Maximum Approved.** Please record the maximum number of participants at WDH and non-WDH sites that have been previously approved by the IRB to be *consented* by this **PI** for the life of the study.
 - B. Total Consented To Date. Provide the total number of participants who have been <u>consented to date by this PI</u>, including any withdrawals or consented screen failures. Withdrawals can include those initiated by the participant, the PI or the sponsor. This number should include all participants who will sign a consent form for this study. (For example, if a participant signs a consent form and is then screened out, that participant should be counted as consented. However, on the continuing review application, that participant would be indicated as a "consented screen failure". If a participant signs a consent document, then is screened out and is instructed to try again in a couple of weeks, and then meets screening criteria, that participant is only counted once. Or, if a participant needs to be reconsented because of new risks or additional information, that participant would only be counted once.)
 - C. Total Consented Since Initial IRB Review or Previous IRB Continuing Review Approval. Provide the total number of participants <u>consented by this PI since the last review</u>, including any withdrawals or consented screen failures. Withdrawals can include those initiated by the participant, the PI or the sponsor. This number should include all participants who will sign a consent form for this study (see 3.B. for details).
 - i. Of the total number of participants consented by this PI since the previous IRB continuing review approval, indicate how many of these participants have completed the study or have participated in the study beyond screening.
 - ii. Of the total number of participants consented by this PI since the previous IRB continuing review approval, indicate how many of these participants consented were withdrawals. Withdrawals can

- include those initiated by the participant, the PI or the sponsor. Include an explanation for each withdrawal (not screen failures) in your summary below in 3.
- **D.** Summary of Study Activities/Status Report. Provide a summary of study activities and a status report of the study to date since the last IRB continuing review approval including any recruitment activities and any new findings. Include any activities at other sites in which the PI is responsible.
- **4. Safety Reporting.** List each unanticipated problem to participants and others and each serious adverse event that has occurred and indicate if these events/problems have been reported previously to the IRB.
- **5. Findings.** List and describe any reports, publications, clinical findings, etc. that have occurred since the last IRB continuing review approval which may impact the study. Note any event or discovery that may change the risk-benefit ratio of the study including favorable reports.
- **6. Complaints.** Describe any complaints about the research project that may have occurred since the last review.
- 7. Study Modifications. Indicate if any modifications have been made to the study since the initial IRB review or any previous IRB continuing review approval occurred. Also indicate if the IRB was notified of those modifications and describe the modifications. Include any attachments as necessary to fully show how the modifications may have affected the study.
- 8. Consent Document. Attach a copy of the currently approved informed consent document(s).
- **9. Investigator's Conflict of Interest Statement.** Identify whether or not the Investigator or any Key Study Personnel have a potential conflict of interest.
- **10. Contact Information.** Provide the Principal Investigator's e-mail address, phone number, fax number and pager number if available. If the contact person if different than the PI, provide the study contact's name, e-mail address, phone number, fax number and pager number.
- 11. Principal Investigator's Assurance Statement. Carefully read this entire statement prior to signing.